Outcomes of the first WHO Product Development for Vaccines Advisory Committee meeting 8-10 Sep 2014

Horizon-scanning of early stage vaccine R&D for SAGE

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Why PDVAC was established?

- No existing group to prioritise across upstream vaccine R&D
- Gap highlighted during Strategic Review of Vaccine Research needs at WHO
- Outcomes will allow IVR to conduct annually updated workplans based on ongoing review of strategic upstream vaccine R&D needs.

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Membership

- Product Development, Vaccine Science, Epidemiology, Public Health, Vaccine Safety, Immunology, Clinical Trials, Vaccinology
- Spanning HIV, TB, malaria, influenza, other respiratory, enterics, bacterial, viral
- All continents (except antarctica)
- Public website with Membership, ToR, DoI, Agenda, Background Documents, Presentations.

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WHO; Gandhi et al, Lancet, 2010

WHO activities to encourage and accelerate development of vaccines in early development

»TRIAL DESIGN: Consensus-building on key endpoints for vaccine evaluation

» Preferred Product Characteristics to guide TPP processes

» Global R&D Roadmaps including strategic goals to articulate priority unmet public health needs

Gap in our processes identified: overseeing activities related to upstream vaccine R&D

- "The Product Development for Vaccines Advisory Committee (PDVAC) will provide strategic advice and recommendations to WHO related to vaccines at the Phase 2 stage of clinical evaluation or earlier. The committee's remit is for disease areas where there is substantial disease burden in low and middle income countries, no vaccines or products currently exist, and there is some ongoing product development activity which may benefit from guidance from WHO."

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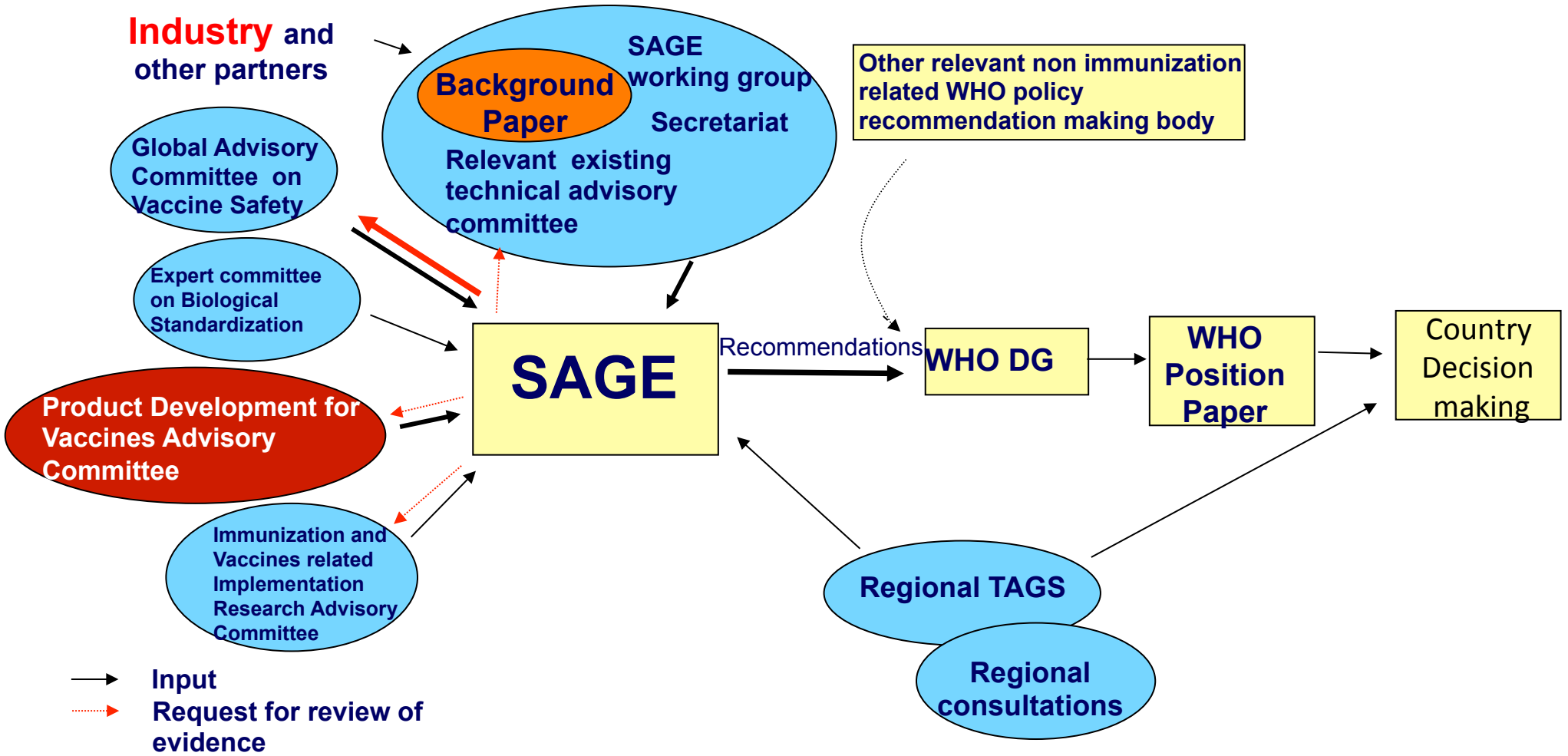
Pathways for WHO Recommendations on Vaccine Use



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Pipeline analyses

- **MODEL:**
  - Identify partner often from Product Development Partnership
  - Provide template
  - Submitted pipeline analysis is reviewed by WHO
  - All have been published on PDVAC website after meeting
  - Core diseases will be reviewed each year including HIV, TB, malaria
  - Committee members ranked priorities according to 3 criteria: **unmet public health need**, likelihood of **product emerging** and **clear role for WHO** activities

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Pipeline analyses

- This year the following 20 pathogen specific areas were requested as pipeline analyses:
- HIV, Tuberculosis, Malaria,
- Universal influenza, RSV
- Group A & B Streptococcus, S. pneumoniae
- Upstream rotavirus, E.coli, Shigella, Paratyphoid, Non-typhoidal salmonella, campylobacter, norovirus
- HSV, Chagas, Leishmaniasis, Schistosomiasis, Human Hookworm

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Key outcomes 1 RSV

RSV highlighted as area where there is major ongoing activity by manufacturers, the technical feasibility exists, and there is a clear role for WHO.

This role is to articulate the public health need in low-income countries, and develop consensus on clinical development pathways to support data generation for global use (not only high income countries).

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Key outcomes 2 Group B Strep

Group B Strep highlighted as area where there is some ongoing activity by manufacturers, the technical feasibility exists, and there is a clear role for WHO.

This role may be to call for further burden of disease data where gaps exist, provide guidance on clinical development pathways and advocate for vaccine development for the unmet need in low income countries

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Key outcomes 3 Group A Strep

Group A Strep highlighted as area where there is little ongoing activity by manufacturers, the technical feasibility exists, and there is a clear role for WHO.

This role may be to develop preferred product characteristics to provide guidance to manufacturers, and call for data to be generated that will support international use of future GAS vaccines

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Key outcomes 4 next gen malaria

Well developed roadmap in place mandates WHO's engagement for next gen vaccines

First Preferred Product Characteristics document being finalized for publication now for second generation malaria vaccines

Regulatory pathway for transmission-blocking vaccines will be a priority area of work

Continued support to highly efficacious morbidity-reducing vaccines

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Key outcomes 5 ETEC, Shigella and Norovirus

These three pathogens were highlighted from the upstream enteric pipeline

Should resources be mobilised WHO guidance on clinical development pathways would be justified

This pathogen area represents a gap in WHO's activities due to lack of resources

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Key outcomes 6 Leishmaniasis, Schistosomiasis, Human Hookworm & Chaga's disease

Very broad area with more work needed on criteria for progression and development pathways

Leishmaniasis might be most feasible as naturally acquired immunity does occur at least for cutaneous leishmaniasis

Community requested to put together document explaining criteria for progression, and clinical development pathway

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Key outcomes 7 Universal Influenza

Remains an important global strategic vaccine R&D area

Role for WHO if resources were mobilized could be to define WHO's preferences for development of an improved seasonal influenza vaccine

- ? Duration of protection of 3-4 years
- ? More strain-transcending but not universal
- WHO may develop a Preferred Product Characteristics document in this area if resources are mobilized to support it, which would be a major scope of work

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Possible new pathogen areas for next year for pipeline analyses

Enterovirus 71
Chikungunya
Meningococcal B
Upstream Dengue, Ebola/Filoviruses

2014-2015 focus on ongoing prioritized activities in:

RSV
Group B Streptococcal
Group A Streptococcal
Malaria, TB, HIV, universal influenza

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